MAY - 2 2005

510(k) # K050495

510(k) SUMMARY
EasySpray and Spray Set for TISSEEL (Fibrin Sealant)

Date Prepared	February 25, 2005
Submitter	Baxter Healthcare Baxter BioScience One Baxter Way Westlake Village, CA 91362
Contact	Ron Lagerquist Senior Manager, Regulatory Affairs
Device Name	Piston Syringe Accessories
Common/Usual/ Classification Name	Piston Syringe Accessories 80 FMF
Device Description	The EasySpray and Spray Set system represents minor design modifications to the TISSOMAT and Spray Set, 510(k) K981089. The purpose of the design modifications is to accommodate a change in the location of the gas on/off function of the system. The original TISSOMAT and Spray Set design includes a foot pedal to turn the gas flow on and off. The EasySpray and Spray Set system moves the control from a foot pedal, to a clip that attaches to the back end of the DUPLOJECT.
Intended Use	The EasySpray and Spray Set are intended for use in the simultaneous application of TISSEEL Two-Component Fibrin Sealant using the DUPLOJECT System
Predicate Device	TISSOMAT and Spray Set K981089
Substantial Equivalence	The EasySpray and Spray Set represent minor design modifications to the TISSOMAT and Spray Set. The design modifications do not affect the intended use of the device or alter the fundamental scientific technology of the system. In addition, there have been no changes to TISSEEL Fibrin Sealant as a result of the device modifications described in this Pre-Market Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2005

Mr. Ronald F. Lagerquist, RAC
Senior Manager, Regulatory Affairs
Baxter Healthcare Corporation
One Baxter Way
Westlake Village, California 91362-3811

Re: K050495
Trade/Device Name: EasySpray and Spray Set
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: February 25, 2005
Received: April 6, 2005

Dear Mr. Lagerquist:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K050495

Device Name: EasySpray and Spray Set

Indications for Use:

The EasySpray and Spray Set are intended for use in the simultaneous application of TISSEEL Two-Component Fibrin Sealant using the DUPLOJECT System.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050495